IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF NORTH CAROLINA
CHARLOTTE DIVISION

VAN SIDNEY BLEVINS, III,	**CIVIL ACTION**
Plaintiff,	**NO: 3:16-cv-785**
v.	
LIVANOVA PLC, SORIN GROUP DEUTSCHLAND GMBH, and SORIN GROUP USA, INC.	**JURY TRIAL DEMANDED**
Defendants.	

CIVIL COMPLAINT

NOW COMES the Plaintiff, Van Sidney Blevins, III, by and through her undersigned attorneys, and for her Complaint against Defendants, LivaNova PLC, Sorin Group Deutschland GMBH and Sorin Group USA, Inc., alleges as follows:

JURISIDCTION AND VENUE

1. This Court has subject matter jurisdiction over this action pursuant to the diverse citizenship of the parties. 28 USCS § 1332(a)(2). Plaintiff is a citizen and resident of the State of South Carolina. Defendant, LivaNova PLC, is a foreign corporation incorporated under the laws of England and Wales with a corporate headquarters in London. Defendant, Sorin Group Deutschland Gmbh, is a foreign corporation headquartered in Munich, Germany. Defendant, Sorin Group USA Inc. has a principal place of business in Arvada, Colorado.

2. Personal jurisdiction exists over Defendants, LivaNova PLC and Sorin Group Deutschland Gmbh, in the U.S. due to the general and specific contacts they maintain in the U.S.

Defendants maintain those contacts presently and did so at all times material to this action. The amount in controversy exceeds $75,000.

3. Venue is proper in this District pursuant to 28 U.S.C. § 1391 as a substantial part of the events and/or omissions giving rise to the Plaintiff's claims emanated from activities within this jurisdiction and Defendants conduct substantial business within this jurisdiction.

THE PARTIES

4. Plaintiff, Van Sidney Blevins, III, is an adult individual and citizen of the state of South Carolina residing at 615 Autumn Circle, Columbia, SC 29206.

5. Defendant LivaNova PLC ("LivaNova") is a foreign for-profit corporation incorporated under the laws of England and Wales with a headquarters in London. LivaNova is a global medical device company specializing in, among other products, devices used in the treatment of cardiovascular diseases. LivaNova pursuant to an October 2015 merger agreement between Sorin Group S.p.A[1] and non-party, Cybertronics, Inc., advised purchasers in the United States it is the responsible party for the Sorin 3T Heater-Cooler System at issue herein. Further, LivaNova has directly communicated with the Food and Drug Administration ("FDA") and other interested parties with respect to safety concerns about the 3T System. *See* the letters attached as Exhibits A through C; Exhibit D, Testimony presented by LivaNova officers and employees before the FDA Circulatory Systems Devices Panel for the Medical Devices Advisory Committee on June 2-3, 2016.

[1] Upon information and belief, Sorin Group S.p.A. was the original holding company of Defendants, Sorin Group Deutschland Gmbh and Sorin Group USA, Inc.

6. Defendant, Sorin Group Deutschland Gmbh ("Sorin") is a foreign for-profit corporation headquartered in Munich, Germany. Sorin initially designed, manufactured, marketed and sold the Sorin 3T Heater-Cooler System. In October 2015, Sorin merged with and into LivaNova, with LivaNova continuing as the surviving company.

7. Defendant, Sorin Group USA, Inc. ("Sorin USA") is a U.S. designer, manufacturer, marketer, seller and distributor of the Sorin 3T Heater-Cooler System, with a principal place of business in Arvada, Colorado. As set forth in LivaNova's Form 10-Q filed with the Security and Exchange Commission, Defendants, Sorin and Sorin USA, are wholly owned subsidiaries of LivaNova. Each Defendant markets and sells products under the LivaNova name.

GENERAL FACTUAL ALLEGATIONS

8. Beginning in October 2015, various hospitals throughout the United States began notifying thousands of major heart, lung and liver surgery patients they had been exposed to a rare and potentially deadly bacteria via Sorin 3T Heater Cooler Systems.

9. The bacteria at issue, *M. Chimaera* and *M. Abscessus*, are subspecies of nontuberculous mycobacterium ("NTM") that occurs naturally in the environment and rarely causes illness. However, NTM poses a unique risk to patients whose organs and chest cavities are directly exposed to the bacteria during surgery.

10. Because NTM is a slow growing bacterium, it generally takes anywhere from two weeks to four years before manifestation of an NTM infection, which most commonly results in pulmonary or cardiovascular disease.

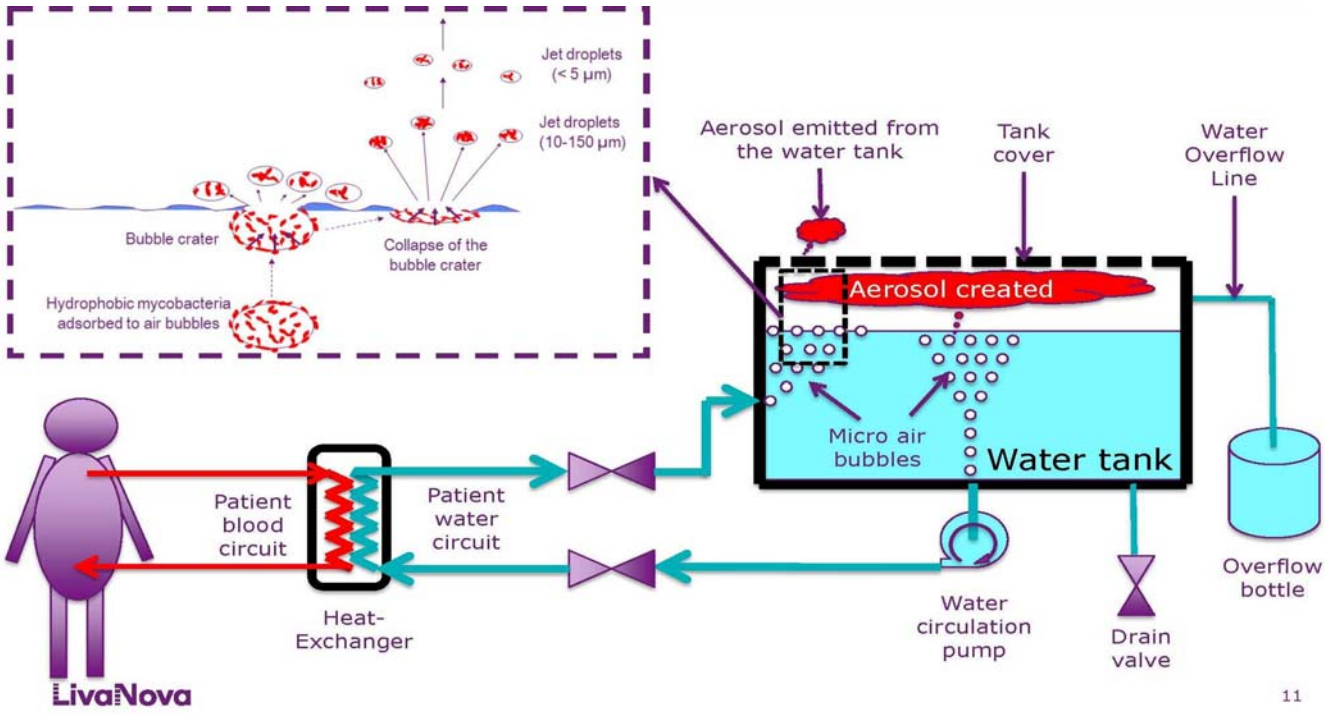
11. Symptoms of NTM infection are non-specific and may include any of the following: fever, pain, heat or pus around a surgical incision, night sweats, joint and muscle pain, weight loss and fatigue.

12. The diagnosis of an NTM infection requires targeted culturing and/or molecular diagnostic testing.

13. While an NTM infection diagnosed early on may be successfully treated with a series of antibiotics, there is a significant risk of death in cases with delayed diagnoses and/or in individuals with considerably weakened immune systems.

A. Defendants' 3T Heater-Cooler Systems as the Infection Source

14. The 3T System regulates blood temperature by circulating water through tubes into a heat exchanger where blood is pumped into separate chambers during surgery. The water tanks and other areas where water pass through aerosolize a vapor containing NTM which exits out of the device and is pushed into the ambient air of the operating room through the System's exhaust fan. When placed in an operating room, the contaminated vapor from the System directly enters the sterile surgical field and the patient's open body.



(taken from LivaNova's presentation to the FDA Circulatory Devices Panel on June 2, 2016, publicly available)

15. The potential for contaminated water from heater-cooler devices to infect patients intraoperatively was recognized by the medical and scientific community as early as November 2002.[2]

16. Invasive cardiovascular infections identified as NTM have been reported in Switzerland, Germany and the Netherlands since 2011.[3]

[2] *See* The Heater-Cooler Unit—A Conceivable Source of Infection, Weitkemper, *et al.*, The Journal of the American Society of Extra-Corporeal Technology, 2002.
[3] ECDC Rapid Risk Assessment, Invasive Cardiovascular Infection by Mycobacterium Chimaera Potentially Associated with Heater-Cooler Units Used During Cardiac Surgery, April 30, 2015, available online at http://ecdc.europa.eu/en/publications/Publications/mycobacterium-chimaera-infection-associated-with-heater-cooler-units-rapid-risk-assessment-30-April-2015.pdf (last accessed on September 13, 2016).

17. A public health investigation in Switzerland following six patient infections since 2011 included microbiological examinations of environmental samples that identified *M. Chimaera* contamination in heater-cooler units, including water samples from inside the units. Samples of the ambient air were positive for *M. chimaera* when the units were running, but negative when they were turned off. [4]

18. In April 2011, the FDA visited Defendant, Sorin Group Deutschland Gmbh in Munchen, Germany for a plant inspection and to discuss safety concerns with several products, including the 3T System which had been approved in 2005 through the 510(k) process. The FDA advised the company that its 3T Systems harbored dangerous bacteria and that it had failed to make a proper risk assessment for cleaning the devices to avoid bacterial infections in patients exposed in the operating room.

19. During this inspection, the FDA advised the company that the bacterial growth charts it used to justify the original instruction for device disinfection every 14 days allowed bacterial overgrowth well in excess of safe standards in just one and a half days. The company admitted to the FDA that its cleaning instructions did not meet these standards and that it had no information to support the cleaning methods it disseminated to U.S. purchasers.

20. On July 15, 2015, Defendants issued a Class 2 Recall of the 3T System because of "[p]otential colonization of organisms, including Mycobacteria, in Sorin Heater Cooler Devices, if proper disinfection and maintenance is not performed per instructions for use."

[4] *Id.*

21. The recall directed customers to follow the new cleaning and disinfection procedures outlined in a Field Safety Notice issued by LivaNova and/or Sorin on June 15, 2015.

22. According to this Field Safety Notice, the company's hygiene concept was "enhanced" by introducing the following modifications:

a) Use filtered tap water when filling the device;

b) To make disinfection easier, switch from three different cleaning procedures (every five days, every two weeks and every three months), to just two (every seven days and every fourteen days);

c) The option to use peracetic acid instead of Clorox for disinfection;

d) Use hydrogen peroxide in low dose for device preservation;

e) Include all external tubing, bottles and buckets in the disinfection process;

f) Change to polyethylene tubing that meets national drinking water standards; and

g) Unused heater-coolers should be disinfected bi-weekly.

23. A month prior to the recall, in May 2015, LivaNova and/or Sorin informed customers that devices that had not been maintained according to the manufacturers' instructions for use ("IFUs") for a long period of time required a mechanical deep disinfection process to remove bacterial colonization, referred to as "biofilm".

24. Upon information and belief, LivaNova and/or Sorin knew or should have known that design and/or manufacturing defects in its 3T System renders it prone to bacterial colonization and transmission, *regardless of the cleaning and disinfection procedures used*.

25. Manufacturing and User Facility Device Experience ("MAUDE") reports, such as one reported to the FDA on July 7, 2016, evidence that even mechanical deep disinfection

followed by the use of filtered water, new water hoses, and three cycles of Defendants' new cleaning procedure fail to eliminate high bacteria counts in the 3T System.[5]

B. Regulatory Agency Responds to NTM Outbreaks Throughout the U.S.

26. The risk of NTM transmission with the 3T System is not unique to any particular hospital or state.

27. In October and November 2015, two Pennsylvania hospitals notified approximately 3600 patients who underwent open heart surgeries between October 1, 2011 and November 5, 2015 of their exposure to NTM through use of the 3T System. On September 20, 2016, a third Pennsylvania hospital, Penn Presbyterian Medical Center in Philadelphia, announced patient infections linked to the 3T System.

28. To date, there have been twenty-one (21) confirmed NTM infections in Pennsylvania which have resulted in five (5) deaths.

29. In February 2016, the University of Iowa Hospitals and Clinics ("UIHC") announced that 1500 of its major heart, lung and liver surgery patients had been exposed to NTM via 3T Systems. To date, UIHC has identified three patient infections, including one death caused by NTM.

30. Hospitals in at least 13 other U.S. states have reported patient infections and/or device contamination with NTM. For example, in May 2016, Swedish Medical Center in

[5] *See also*, ECDC Rapid Risk Assessment, *supra* ("In Switzerland, cleaning and decontamination of the heater-cooler units was followed by recontamination. A new heater-cooler unit that initially tested negative for *M. Chimaera* at the hospital tested positive three months after purchase and installation.")

Seattle, Washington issued letters notifying certain cardiac bypass patients that it had tested and found NTM in several of its 3T Systems.

31. Many hospitals have either discontinued using the 3T System or have moved them into separate rooms to prevent contaminated aerosols from reaching the surgical field.

32. On October 21, 2015, following the NTM outbreak in Pennsylvania, the U.S. Centers for Disease Control and Prevention ("CDC") issued an Interim Practical Guidance communication to raise awareness among health departments, healthcare facilities and providers of the association between NTM infections and the use of heater-cooler devices.

33. On December 29, 2015, the FDA sent LivaNova a warning letter advising the company that its 3T Systems were subject to refusal of admission into the U.S. until it resolved several FDA violations, including the FDA's determination that the 3T Systems were adulterated[6] and misbranded and lacked requisite safety validation for several design changes to both the device itself as well as a series of revised disinfection instructions. The FDA's findings were based on its inspections of the company's Munchen, Germany and Arvada, Colorado production facilities.

34. In the letter, the FDA identified various design change orders dating back to December 11, 2012 which had never been documented, validated and/or submitted to the FDA for approval.

[6] Under the Federal Food, Drug and Cosmetic Act, a medical device is "adulterated" if the methods used in, or the facilities or controls used for their manufacture, packing, storage or installation are not in conformity with current good manufacturing practice requirements of the Quality System regulation.

35. The letter also identified several changes to the disinfection instructions, dating back to December 20, 2011, which had never been reported to the FDA and which, like the current disinfection instructions, lacked proper efficacy validation.

36. In April 2016, a Euro Surveillance study following environmental investigations conducted between July 2014 and June 2015 determined that certain 3T Systems manufactured at LivaNova's Munich, Germany production facility were contaminated with NTM on the production line or elsewhere at Defendants' manufacturing facility.

37. A June 1, 2016 FDA Safety Communication following the Euro Surveillance findings noted that "this paper suggests a direct link between the *M. Chimaera* to which European patients were exposed and became infected during open-chest cardiac surgery, and one specific heater-cooler model—the 3T." The FDA cautioned U.S. purchasers of the 3T that if they purchased their units before September 2014 they may have been shipped from Defendants' factory contaminated with *M. Chimaera*.[7]

38. In June 2016, a study published in the Journal of Emerging Infectious Diseases confirmed the airborne transmission of NTM via 3T Systems due to the ability of the System's exhaust fan to disrupt the ultraclean air ventilation systems of operating rooms. According to the study, aerosolization from the 3T carried *M. Chimaera* particles a distance of up to 5 meters from the device.

[7] June 1, 2016 FDA Safety Communication, available at http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm504213.htm (last accessed on September 20, 2016).

39. On June 2-3, 2016, the FDA hosted a Circulatory System Devices Panel for the Medical Devices Advisory Committee to address the public health risk posed by heater-cooler devices, and in particular, the 3T System.

40. During this Panel, the FDA noted that nearly 90% of the Medical Device Reports ("MDR") it received between January 2010 and February 2016 citing device contamination and patient infection were attributed to the 3T System.

MDRs by Manufacturer, Brand Name and User Facility (US vs. OUS)

MDRs by Manufacturer and UF				
Manufacturer and Brand Name	Total Number of MDRs	Number of User Facilities Represented in the MDRs		
		US	OUS	Total
LivaNova/Sorin** Stockert 3T	160	15	35	50
Maquet HCU20, HCU30 & HCU40	9	0	5*	5*
Cincinnati Sub-Zero 333W and Hemotherm	3	2*	0	2*
Terumo HX2	8	1*	0	1*
Total	180	16 (2*)	39 (1*)	55 (3*)

*Note that 3 UF reported devices from 2 different manufacturers
**LivaNova/Sorin has approximately 60% of the market share for this type of device

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41. During this Panel, a LivaNova representative admitted that the company was in the process of retrofitting existing 3T Systems with new design features, including, but not limited to, changing tubing materials from PVC to polyethylene to limit biofilm formation and the introduction of plugs in the water circuit to prevent standing water.

42. On October 13, 2016, the CDC released the results of genome sequencing studies confirming that patient infections in Pennsylvania and Iowa shared an "identical fingerprint" and were directly linked to Defendants' Munich, Germany manufacturing site.[8]

43. That same day, the FDA issued an updated Safety Communication instructing hospitals throughout the country to discontinue using 3T Systems manufactured before September 2014 due to evidence of "point source contamination at the production site".[9]

C. Factual Allegations Specific to Plaintiff, Van Sidney Blevins, III

44. On June 11, 2015, Van Sidney Blevins, III (hereinafter "Sidney Blevins") underwent an orthotopic liver transplant at Carolinas Medical Center-Charlotte ("CMC") to treat end-stage liver disease.

45. Upon information and belief, a 3T Heater Cooler System was used during Sidney Blevins' liver transplant surgery.[10]

46. On June 19, 2015, Sidney Blevins returned to CMC with complaints of fever, abdominal pain and diarrhea. A CT scan revealed an enlarged spleen, abdominal ascites and an intra-abdominal abscess. Multiple cultures returned negative and Sidney Blevins' fever resolved with IV antibiotics. He was discharged on June 22, 2015 with prophylactic antibiotics.

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[8] *See* CDC Morbidity and Mortality Weekly Report for October 14, 2016, available online at https://www.cdc.gov/mmwr/volumes/65/wr/mm6540a6.htm?s_cid=mm6540a6_w (last accessed on October 14, 2016)

[9] *See* October 13, 2016 "UPDATE: Mycobacterium Chimaera Infections Associated with LivaNova PLC (formerly Sorin Group Deutschland GmbH) Stockert 3T Heater-Cooler System: FDA Safety Communication", available online at http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm520191.htm (last accessed on October 14, 2016)

[10] Plaintiff's counsel was advised by a member of Carolinas Medical Center's liver transplant program that a 3T System was routinely used for all liver transplants performed at the hospital.

47. On August 26, 2015, Sidney Blevins returned to CMC with complaints of persistent fever, abdominal pain and poor wound healing. A repeat CT scan revealed ongoing enlargement of the spleen and intra-abdominal abscess. Infectious disease physicians expressed concern over persistent fevers thought to be related to slow wound healing and superficial abscess. Sidney Blevins was discharged on August 27, 2015 with instructions to continue antibiotics, monitor for fevers daily and follow up with his physician.

48. On September 14, 2015, Sidney Blevins returned to CMC with complaints of flu like symptoms, including fatigue with fever, chills and night sweats, and persistent intra-abdominal abscess. On September 16, 2015, Sidney Blevins underwent a wound debridement and subsequent cultures returned positive for acid fast bacteria. Cultures from the abdominal wall proximal to his liver ultimately grew *Mycobacterium abscessus* (NTM). Sidney Blevins was discharged on September 25, 2015 with IV antibiotics and a wound vac to be monitored by home health care.

49. On October 9, 2015, Sidney Blevins was admitted to CMC for severe fever, chills, nausea and vomiting. He was observed for several days and released on October 12, 2015 with adjustments to his antibiotic regiment.

50. On October 20, 2015, Sidney Blevins was readmitted to CMC with elevated liver function as well as severe nausea, difficulty tolerating food, jaundice and skin irritation. During this hospitalization, Sidney Blevins was noted to have suffered antibiotic induced injuries to his kidneys and liver and severe malnutrition. He was discharged on October 30, 2015 with additional changes to his antibiotic regimen.

51. On December 4, 2015, Sidney Blevins was readmitted to CMC with complaints of abdominal wound drainage and increased forgetfulness. He was discharged home on December 6, 2015 with instructions to continue antibiotics.

52. On December 9, 2015, Sidney Blevins was readmitted to CMC with fevers, increased white blood cell counts and abdominal wound cellulitis with drainage. At this point, it was felt that his treatment plan was failing and Sidney Blevins was scheduled for surgery. On December 10, 2015, Sidney Blevins underwent a second debridement surgery with wound vac placement to treat abdominal wall NTM infection. He was discharged on December 15, 2015 with a wound vac and home health care script.

53. On January 14, 2016, Sidney Blevins was readmitted to CMC with persistent fever, chills and fatigue. Sidney Blevins underwent multiple blood transfusions and on January 21, 2016, physicians at CMC performed CT guided abdominal drainage. During this hospitalization, Sidney Blevins had a feeding tube placed to treat severe malnutrition. Sidney Blevins was discharged from CMC on February 19, 2016 with instructions to continue a maximum dose of IV antibiotics.

54. Sidney Blevins was readmitted to CMC on March 9, 2016 to be treated for anemia and significant blood cell abnormalities caused by his antibiotics. Sidney Blevins was administered packed red blood cells and released from CMC on March 10, 2016 with changes to his antibiotic regimen.

55. Despite aggressive, ongoing antibiotic treatment for the past 13 months, Sidney Blevins is still infected with NTM and has only recently seen improvements in his overall health.

COUNT I
Negligence- Design Defect

56. Plaintiff incorporates by reference the preceding paragraphs as if fully set forth herein.

57. The 3T System is a product within the meaning of N.C. Gen. Stat. §99B-6 and other North Carolina products liability law.

58. The 3T System was expected to reach, and did reach, users and/or consumers, including Plaintiff Sidney Blevins, without substantial change in the defective and unreasonably dangerous condition in which it was sold or distributed.

59. Under North Carolina products liability law, Defendants, LivaNova, Sorin and Sorin U.S.A, owed Plaintiff Sidney Blevins, a duty to exercise reasonable care in designing and testing the 3T System.

60. Defendants, LivaNova, Sorin and Sorin U.S.A. designed the 3T System for the purpose of heating and cooling patient blood during major heart, lung and liver surgeries.

61. At all times material, the 3T System was used in a manner intended and/or foreseeable to the Defendants.

62. A patient or consumer using the 3T System would reasonably expect the device to be free of significant defects.

63. The 3T System, as designed by the Defendants, colonizes bacteria, including NTM.

64. The 3T System, as designed by the Defendants, directly transmits bacteria, including NTM, to patients during invasive surgical procedures.

65. The foreseeable risks of using the 3T System, particularly severe bacterial infection and/or death, significantly outweigh the benefits conferred upon patients by using the 3T System during invasive surgical procedures.

66. As of the time the 3T system left the control of the Defendants, safer, practical, feasible and otherwise reasonable alternative designs existed for the 3T System which would have eliminated or substantially reduced the risk of bacterial colonization and/or transmission of such bacteria to patients undergoing invasive surgical procedures without reducing the utility of the 3T system.

67. Reasonable and feasible alternative designs include, but are not limited to, measures to direct airflow away from the surgical field (i.e. a housing unit for the exhaust vent), reducing the force at which air is vented from the System to a rate of less than 1000 cubic feet per minute, water reservoir isolation by using closed loop fluid management, an open water design to prevent inaccessible airspace, removable lids and parts for easy disinfection, disposable tank liners to prevent biofilm formation, and/or internal pasteurization or UV features to kill bacteria.

68. The failure to use feasible, reasonable alternative designs that eliminate bacterial colonization and the aerosolization of bacteria into the ambient air of operating rooms renders the 3T System unreasonably unsafe for its intended purpose.

69. Defendants knew or should have known as early as 2002 that NTM, or other harmful bacteria, could colonize within the 3T System and be spread to patients during invasive surgical procedures through the exhaust vent.

70. The design of the 3T at the time it left the control of the Defendants was so unreasonable that a reasonable person or user of the product, aware of the facts as described herein, would not likely use the 3T system during invasive surgical procedures because of its unsafe design.

71. Plaintiff Sidney Blevins' NTM infection was proximately caused by Defendants' acts and omissions of negligence, which include, but are not limited to, the following:

a) Failing to conduct adequate safety and efficacy testing before placing the 3T System into the stream of commerce;

b) Failing to timely establish procedures for reviewing the design of the 3T System after receiving information that patients were developing bacterial infections as a result of invasive surgical procedures using the System;

c) Failing to timely establish procedures for validation or, where appropriate, review and approval of design change orders for the 3T System before their implementation as required under 21 CFR 820.30(i); and

d) Failing to design or redesign the 3T System to eliminate or mitigate bacterial colonization and/or transmission of such bacteria during invasive surgical procedures using the System.

72. Plaintiff, Sidney Blevins, was proximately harmed by the aforesaid design defects in the 3T System as described above.

COUNT II
Negligence-Manufacturing Defect

73. Plaintiff incorporates by reference the preceding paragraphs as if fully set forth herein.

74. The 3T System is a product within the meaning of N.C. Gen. Stat. §99B-6 and other North Carolina products liability law.

75. The 3T System was expected to reach, and did reach, users and/or consumers, including Plaintiff, Sidney Blevins, without substantial change in the defective and unreasonably dangerous condition in which it was sold or distributed.

76. Defendants, LivaNova, Sorin and Sorin U.S.A. manufactured the 3T System for the purpose of heating and cooling patient blood during major heart, lung and liver surgeries.

77. At all times material, the 3T System was used in a manner intended and/or foreseeable to the Defendants.

78. Neither the Defendants' intended design, nor the intended manufacturing process for the 3T System, included a product that was contaminated with NTM or other harmful bacteria on the production line, elsewhere at Defendants' production facilities, or through foreseeable and intended use.

79. The 3T System, as manufactured by the Defendants, including the one used in Plaintiff's surgery, was contaminated with bacteria, including NTM, during the manufacturing process and/or through foreseeable and intended use, and was therefore at variance from the intended design which rendered it defective and unreasonably dangerous.

80. Plaintiff Sidney Blevins' NTM infection was proximately caused by Defendants' acts and omissions of negligence, which include, but are not limited to, the following:

a) Failing to timely establish procedures or practices to prevent the 3T System from being contaminated with NTM on the production line or elsewhere at Defendants' production facilities;

b) Manufacturing and selling the 3T System with NTM contamination that occurred on the production line or elsewhere at Defendants' production facilities; and

c) Failing to ensure proper workmanship, materials and labeling for the 3T System.

81. Plaintiff, Sidney Blevins, was proximately harmed by the aforesaid manufacturing defects in the 3T System as described above.

COUNT III
Negligence- Warnings Defects

82. Plaintiff incorporates by reference the preceding paragraphs as if fully set forth herein.

83. The 3T System is a product within the meaning of N.C. Gen. Stat. §99B-5 and other North Carolina products liability law.

84. The 3T System was expected to reach, and did reach, users and/or consumers, including Plaintiff, Sidney Blevins, without substantial change in the defective and unreasonably dangerous condition in which it was sold or distributed.

85. Defendants, LivaNova, Sorin and Sorin U.S.A, owed Plaintiff, Sidney Blevins, a duty to exercise reasonable care in marketing, advertising, promoting, distributing and/or selling the 3T System.

86. Defendants, LivaNova, Sorin and Sorin U.S.A. marketed, advertised and promoted the 3T System for the purpose of heating and cooling patient blood during major heart, lung and liver surgeries.

87. As of the time the 3T System left the control of the Defendants, the Defendants knew or should have known as early as 2002 that NTM, or other harmful bacteria, could colonize within the 3T System and be spread to patients during surgery through the exhaust vent as previously described herein, but the Defendants did not adequately warn patients or users about the risk of colonization with NTM or other harmful bacteria, nor did they adequately instruct users of the 3T system with regard to proper cleaning and disinfection procedures.

88. The 3T system used during Plaintiff Sidney Blevin's surgery, which was sold without such warnings and instructions rendered the 3T system unreasonably dangerous and it use posed a substantial risk of harm to reasonably foreseeable patients, including Plaintiff Sidney Blevin.

89. Between the time of the sale of the 3T system and its use during Plaintiff's surgery, the Defendants knew or should have known of the defective and dangerous condition, as described herein, yet the Defendants failed to provide warnings about the potential for colonization with NTM or other bacteria, and they failed to provide instructions for proper cleaning and disinfection procedures.

90. Plaintiff Sidney Blevins' NTM infection was proximately caused by Defendants' acts and omissions of negligence, which include, but are not limited to, the following:

91.

a) Failing to provide proper cleaning and disinfection procedures for the 3T System;

b) Failing to conduct proper validation studies to demonstrate the safety and efficacy of cleaning and disinfection procedures for the 3T System;

c) Failing to warn patients like Sidney Blevins and/or purchasers of the 3T System that the System colonized bacteria and unnecessarily transmitted it into the ambient air of operating rooms during invasive surgical procedures;

d) Failing to timely notify known purchasers of the 3T System that patients could be exposed to NTM during invasive surgical procedures;

e) Failing to alert hospitals and patients to promptly test for NTM infection when patients present with fever, pain, heat or pus around a surgical incision, night sweats, joint and muscle pain, weight loss and fatigue after invasive surgical procedures using the 3T System; and

f) Failing to timely notify known purchasers of the 3T System to relocate the device from the operating room during invasive surgical procedures to prevent patient transmission of NTM.

92. Plaintiff, Sidney Blevins, was proximately harmed by the aforesaid warnings defects in the 3T System as described above.

Damages

93. Plaintiff incorporates by reference the preceding paragraphs as if fully set forth herein.

94. Since his NTM diagnosis, Sidney Blevins has suffered persistent pain from an infected surgical site wound, chronic fevers, nausea, fatigue, malnutrition and weight loss as well as antibiotic induced kidney and liver injuries.

95. As a direct and proximate result of Defendants' negligence and liability producing conduct as described herein, Sidney Blevins acquired an NTM infection, forcing him to undergo numerous painful medical procedures and treatment.

96. As a direct and proximate result of Defendants' negligence and liability producing conduct as described herein, Plaintiff, Sidney Blevins, has been forced to seek medical attention and treatment through private physicians, hospitals and other medical providers at considerable expense and, as a further result of his injuries, the Plaintiff has suffered severe physical pain and mental anguish and will continue to suffer severe physical pain and mental anguish in the future.

97. Plaintiff Sidney Blevins is informed and believes, and so alleges on information and belief, that he will continue to incur substantial medical expenses over the remainder of his natural life for treatment of injuries received as a direct and proximate result of Defendants' negligence. Plaintiff Sidney Blevins is entitled to recover of Defendants, jointly and severally, all amounts he will incur for future medical expenses.

98. As a direct and proximate result of Defendants' negligence and liability producing conduct as described herein, Plaintiff, Sidney Blevins, suffered and continues to suffer from excruciating and agonizing physical pain and emotional suffering.

99. As a direct and proximate result of Defendants' negligence and liability producing conduct as described herein, Plaintiff Sidney Blevins was unable to perform the usual duties of his occupation for a substantial period of time, thereby resulting in a substantial loss of earnings and/or earning capacity. Plaintiff Sidney Blevins is informed and believes, and so alleges on information and belief, that his ability to earn wages in the future has been diminished by his

injuries and that he will suffer a substantial loss of earning capacity over the remainder of his work life.

100. Plaintiff, Sidney Blevins, was in no way responsible for his injuries.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff, Sidney Blevins, respectfully prays the Court for the following relief:

A. That the Plaintiff have and recover of the Defendants, individually, vicariously, jointly and severally, a money sum to be determined by a jury for his personal injuries and damages;

B. For such other damages as may be permitted pursuant to the laws of the State of North Carolina, together with interest thereon, costs of suit and reasonable attorneys' fees, as permitted by law;

C. An award of pre-judgment and post-judgment interest, as provided by law;

D. Leave to amend this Complaint to conform to the evidence produced at trial; and

E. Such other relief as may be appropriate under the circumstances.

JURY TRIAL DEMANDED

Plaintiff demands a trial by jury on all issues so triable.

Dated: November 14, 2016 Respectfully submitted,

CHARLES G. MONNETT III & ASSOCIATES

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